

Federal Advisory Committee (FAC) Membership Balance Plan

Please read the [Federal Advisory Committee Membership Balance Plan Guidance](#) prior to completing this form

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES/OFFICE OF THE SECRETARY/OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

(1) FEDERAL ADVISORY COMMITTEE NAME

State the legal name of the FAC

Secretary's Advisory Committee on Human Research Protections

(2) AUTHORITY

Identify the authority for establishing the FAC

42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Secretary's Advisory Committee on Human Research Protections (SACHRP) is a discretionary Federal advisory committee

(3) MISSION/FUNCTION

Describe the mission/function of the FAC

SACHRP advises, consults with, and makes recommendations on matters pertaining to the continuance and improvement of functions within the authority of the Department of Health and Human Services (HHS) directed toward protections for human subjects in research.

(4) POINTS OF VIEW

Based on understanding the purpose of the FAC,

- (a) describe the process that will be used to ensure the committee is balanced, and identify the categories (e.g. individual expertise or represented interests) from which candidates will be considered;*
- (b) consider indentifying an anticipated relative distribution of candidates across the categories; and*
- (c) explain how a determination was made to appoint any individuals as Special Government Employees or Representative members*

SACHRP consists of 11 voting public members, including the Chair, who are selected from among individuals possessing demonstrated experience and expertise in any of the several disciplines and fields pertinent to human subjects protection and/or clinical research. The 11 voting public members are special Government employees.

(5) OTHER BALANCE FACTORS

List any other factors your agency identifies as important in achieving a balanced FAC

Every effort is made to ensure that the Committee membership is fairly balanced in terms of points of view represented and the Committee's function. Consideration is given to ensure that there is a broad representation of geographic areas, gender, race, ethnicity, and disability.

(6) CANDIDATE IDENTIFICATION PROCESS

Summarize the process intended to be used to identify candidates for the FAC, key resources expected to be tapped to identify candidates and the key persons (by position, not name) who will evaluate FAC balance. The summary should:

- (a) describe the process*
- (b) identify the agency key staff involved (by position, not name)*
- (c) briefly describe how FAC vacancies, if any, will be handled by the agency; and*
- (d) state the membership term limit of FAC members, if applicable*

A notice will be published in the Federal Register to solicit the applications from individuals who are interested in being considered for appointment to the Committee. The applications received in response to the solicitation are reviewed by the appropriate program staff in the Office for Human Research Protections (OHRP), which is the program office within Office of the Assistant Secretary for Health that has been given responsibility for providing management support for SACHRP activities. In addition to OHRP staff, a review panel is assembled, that consist of representatives from HHS agencies and other Federal agencies that have involvement in human subjects research and protections. The criteria used for selecting potential candidates includes relevant professional degrees and level of expertise in human subjects protection areas; scientific and academic background; research ethics experience; institutional (IRB) experience; prior government (federal, state, local) experience; relevant committee experience; number of publications (primarily first authored and peer reviewed); investigator experience, and socio-behavioral research experience. Qualified candidates are selected from this review. The names and pertinent information on the qualified candidates are submitted to the HHS Assistant Secretary for Health to review and give approval for information on the selected candidates to be forwarded in a draft nomination request to the HHS Committee Management Office for the necessary review. The draft nomination request is forwarded to HHS Committee Management Office for subsequent review and vetting. The draft nomination request is reviewed by the HHS White House Liaison, Chief of Staff, and other senior level officials in Immediate Office of the Secretary for a determination to be made about the qualifications of the selected candidates to be nominated for appointment. If it is approved for the selected candidates to be nominated for appointment to the Committee, then the formal nomination request to the Secretary is prepared for the necessary action to be taken. Committee members are appointed to serve for overlapping terms of up to four years. Terms of more than two years are contingent upon renewal of the Committee's charter by appropriate action prior to its expiration. Any member appointed to fill a vacancy for an unexpired term shall be appointed only for the remainder of that term. A member may serve no more than 180 days after the expiration of the member's term if a successor has not taken office. If a vacancy occurs, then a notice is published in the Federal Register again and/or applications received in response to the most recent solicitation are reviewed again. If no qualified candidate is identified from this review, then information about the vacant position is widely disseminated to organizations interested in human subjects protection and research, as well as the general public in an effort to locate potential candidates who are qualified to be considered for nomination and appointment to the Committee.

(7) SUBCOMMITTEE BALANCE

Subcommittees subject to FACA should either state that the process for determining FAC member balance on subcommittees is the same as the process for the parent FAC, or describe how it is different*

**This is relevant to those agencies that require their subcommittees to follow all FACA requirements*

The process that is used to determine the appropriate balance for membership on the parent committee will be used for any subgroup that is established to assist the SACHRP.

(8) OTHER

Provide any additional information that supports the balance of the FAC

Not applicable.

(9) DATE PREPARED/UPDATED

Insert the actual date the Membership Balance Plan was initially prepared, along with the date(s) the Plan is updated

Prepared: 07/16/2012; Updated: 09/05/2014, 09/14/2016, 9/19/2016